

American Heart Association comment: FDA announces safety changes on labeling for some statins

February 29 2012

The United States Food and Drug Administration (FDA) [announced it is revising safety information](#) on the labels of some statins (cholesterol lowering drugs).

Statins are a class of drugs that work in the liver to prevent the formation of cholesterol. They are most effective at lowering the LDL (bad) cholesterol, but also have modest effects on lowering triglycerides ([blood fats](#)) and raising HDL (good) cholesterol. High cholesterol is a risk factor for cardiovascular disease and stroke.

The FDA changes to the statin labels include:

- Revising the drug labels to remove the need for routine periodic monitoring of [liver enzymes](#) in patients taking statins.
- Including labeling information about some patients experiencing memory loss and confusion.
- Warning healthcare professionals and patients of the potential risk of increased [blood sugar levels](#) and of being diagnosed with type 2 diabetes mellitus.

The announcement also alerts [health care professionals](#) to new recommendations in the lovastatin label, including drug interactions like those with drugs used to treat HIV (protease inhibitors).

"The FDA's announcement on the label changes does not question the benefit of statins to lowering cholesterol, but it does provide patients and healthcare providers the most current information about the safe use of statins," said Gordon F. Tomaselli, M.D., president of the [American Heart Association](#).

"Not surprising, but important for practitioners with regard to routine liver function test screening, which is no longer recommended, but should be done at baseline and for symptoms. This will change practice although I will remain vigilant in people with prior history of liver disease, people who drink or who are taking multiple drugs metabolized by the liver. Also, the contraindications of use of in particular anti-HIV drugs with Mevacor (lovastatin) are important to reemphasize as is the known but infrequent increase in blood sugar in patients taking statins."

Tomaselli says "while we recommend healthy people focus on prevention using lifestyle changes rather than drug therapy whenever possible, for some people, lifestyle changes aren't enough. As with all therapies, the decision to use statins for primary or secondary prevention must include careful consideration of the risks and benefits, side-effects and cost. Working with your healthcare provider to be sure you're doing what you need to do to stay healthy is the best approach."

More information: FDA news release - www.fda.gov/NewsEvents/Newsroom/NewsEvents/ucm293623.htm

Cholesterol lowering drugs information - www.heart.org/HEARTORG/Condition/Cholesterol-Lowering-Drugs/Article.jsp?M=305632

Provided by American Heart Association

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